Workgroup 2
Innovative Approaches to Evaluate Performance

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WHAT ARE THE WAYS BY WHICH PT/EQA PROGRAMS COULD EVALUATE SPECIFIC PRE-ANALYTIC STEPS IN THE MEDICAL LABORATORY'S TESTING PROCESS?

- Evaluate information on the Collection of Specimens (Samples)
  - Patient Preparation
  - Correct identification of the patient
  - Requirements for collectiLabelingen container
    - Labeling
    - Volume
    - Special requirements
  - Requisition document

WHAT ARE THE WAYS BY WHICH PT/EQA PROGRAMS COULD EVALUATE SPECIFIC PRE-ANALYTIC STEPS IN THE MEDICAL LABORATORY'S TESTING PROCESS?

- Evaluate the transport of specimens
  - Time in transit
  - Packaging
  - Temperature of storage
  - Precautions to preserve the integrity of the target analyte during transport
- Use duplicate PT/EQA samples to check effect of pre-analytical processing

WHAT ARE THE WAYS BY WHICH PT/EQA PROGRAMS COULD EVALUATE SPECIFIC PRE-ANALYTIC STEPS IN THE MEDICAL LABORATORY'S TESTING PROCESS?

- Evaluate the laboratory reception and accessioning process
  - Criteria for acceptance and rejection
  - Re-labeling
  - Secondary sample preparation
- Check process and procedures for traceability
  - Primary sample to the patient
  - Secondary samples to primary samples

WHAT ARE THE WAYS BY WHICH A PT/EQA PROGRAM COULD EVALUATE SPECIFIC POST-ANALYTIC STEPS IN THE MEDICAL LABORATORY'S TESTING PROCESS?

- Evaluate the report generation process
  - Result review and acceptance
    - Verification of calculations
  - Fitness for purpose of the format of the report
  - Appropriateness of the reference intervals
  - Interpretive components
  - Amendment of reports
- Examine the integrity and security of the Laboratory Information System and the linkage with the HIS

WHAT ARE THE WAYS BY WHICH A PT/EQA PROGRAM COULD EVALUATE SPECIFIC POST-ANALYTIC STEPS IN THE MEDICAL LABORATORY'S TESTING PROCESS?

- Assess the report distribution process
  - Authority for release
  - Distribution mechanisms
  - Confidentiality
  - Turn around time
  - Critical value reporting

WHAT ARE SOME OF THE WAYS THAT POINT-OF-CARE TESTING AND OTHER NEAR PATIENT TESTING CAN BE EVALUATED?

- Regular internal audits
- Regular testing of QC materials with appropriate values especially for qualitative testing (+10% above cut-off)
- Use of 3rd party QC materials where available
- Protocols for education and training
- Defined oversight and/or responsibility for testing
- POC device manufacturers role in product QA (recommendations/materials)

WHAT CAN BE DONE TO EVALUATE PERFORMANCE FOR ANALYTES/TESTS FOR WHICH TRADITIONAL PT/EQA IS NOT AVAILABLE?

- Split sample testing
- Blind sample testing
- Repeat sample testing with time
- Sharing samples
- Referral of previously tested material to a reference or reference method laboratory

WHAT CAN BE DONE TO EVALUATE PERFORMANCE FOR ANALYTES/TESTS FOR WHICH TRADITIONAL PT/EQA IS NOT AVAILABLE?

- Manufacturers provide appropriate QC materials
- Assistance from WHO, IFCC, CDC
- An intra- or inter-facility QC program
- Use of artificial challenge samples

HOW COULD THE INTERNET, FAX, TELEPHONE, OR OTHER MEANS BE USED TO PROVIDE PT/EQA RESULTS MORE RAPIDLY?

- Aggregate information from PT/EQA should be made public
  - for educational purposes and
  - for assessing information used to determine the performance of the assays in the field.
- web based programs will provide more rapid access than traditional mail-outs
- benefits may not be readily achievable at the moment.
- use internet to receive and report proficiency test results.

HOW COULD THE INTERNET, FAX, TELEPHONE, OR OTHER MEANS BE USED TO PROVIDE PT/EQA RESULTS MORE RAPIDLY?

- List-servers for PT/EQA participants and organizers could be used to share information such as the poor performance of an assay.
- Data mining issues; standardization of formats to access critical information.
- Education

IN WHAT WAYS CAN THE INTERNET, FAX, TELEPHONE OR OTHER TECHNOLOGIES BE USED TO MEET THE NEEDS FOR PT/EQA PROGRAMS IN RESOURCE-LIMITED COUNTRIES?

- There is insufficient infrastructure currently available
  - Assist resource limited countries to determine their needs
  - Call on agencies such as CDC, PAHO, WHO and others to lobby organizations to assist financially.
  - Develop a standard approach which takes into account different levels of resources
- If available, internet would provide access to training and education in IT and quality management procedures.

WHAT CONCEPTS IN PT/EQA PROGRAMS COULD BE INTRODUCED IN A RESOURCE-LIMITED COUNTRY BEFORE A TRADITIONAL PROGRAM IS DEVELOPED?

- External quality assessment audit—external review of laboratory operational structure
  - Testing menu
  - SOP's
  - QA/QC practices
  - Educational qualifications and training of personnel
  - Inter-laboratory cv's to detect gross analytical errors or bias
  - Offer recommendation on best practices

WHAT CONCEPTS IN PT/EQA PROGRAMS COULD BE INTRODUCED IN A RESOURCE-LIMITED COUNTRY BEFORE A TRADITIONAL PROGRAM IS DEVELOPED?

- Random re-testing of patient samples
  - Performed by “mentor” laboratory
  - Intra-laboratory review—“round-robin” review
  - Use to establish standardized protocols
- Use less costly EQA challenge materials
  - Share control material among laboratories
  - Use simplified panels with a limited analyte range
  - Use materials donated by PT providers
  - Simplified matrix/photographs, dry challenges

FOR WHICH LABORATORY DISCIPLINES MIGHT SUCH APPROACHES BE UCCESSFUL?

- All disciplines
- Microbiology smears, hematology smears, other tests that have a stable specimen
- Clinical chemistry (selected analytes), immunology/serology, antigen detection

FOR WHAT TYPES OF LABORATORY TESTING WOULD IT BE BETTER TO RE-ANALYZE PATIENT SPECIMENS RATHER THAN SENDING OUT SAMPLES TO DETECT POOR LABORATORY PERFORMANCE?

- Advantages and disadvantages of both
- Internal re-examination advantageous when specimen integrity may be compromised
- External re-examination depends on an established network
- Both can evaluate specimen preparation, internal provides more rapid information

HOW WOULD THE COST COMPARE WITH TRADITIONAL PT/EQA AND WHAT WOULD BE THE LOGISTICAL CONCERNS ABOUT ESTABLISHING A RE-EXAMINATION OF PATIENT SPECIMENS?

- Internal re-examination has less cost for “experts” and test fees but increases local labor costs
- Remote location of a laboratory is a factor regarding shipping costs
- Internal process likely will require a greater number of re-examinations than external for the same level of confidence

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